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FDA REGULATION UNDER FOOD ADDITIVE LAW

The Food and Drug Administration published in the Federal Register of January 19 a regulation listing substances that are generally recognized as safe within the meaning of the 1958 Food Additives Amendment to the Food and Drug Act. This is the second such list issued by FDA.

Pursuant to the authority vested in the Secretary of Health, Education, and Welfare by the Federal Food, Drug, and Cosmetic Act (secs. 409, 701, 52 Stat. 1055, 72 Stat. 1785; 21 U.S.C. 348, 371) and delegated to the Commissioner of Food and Drugs by the Secretary (23 F.R. 9500), and after having considered all comments on the proposed order published in the *Federal Register* of April 21, 1959 (24 F.R. 3085), containing a list of spices, seasonings, essential oils, oleoresins, and natural extractives generally recognized as safe within the meaning of section 409 of the act, the Commissioner has concluded that the substances in that list, with the exception of cinchona bark (red), cinchona bark (yellow), orris root, orris (concrete, liquid), quinine, wintergreen, and

methyl salicylate are generally recognized as safe. The failure to include these substances in the list published in this order does not indicate that these substances as they are used for flavoring are not safe. However, it is concluded that in the case of the first five there is not a general recognition of their safety without adequate restrictions being placed upon their use as flavoring agents, through the promulgation of appropriate regulations. In the case of methyl salicylate and wintergreen, it was decided to delay any determination on the question of general recognition of safety pending the completion of pharmacological studies of methyl salicylate. These studies have been underway for some time and are expected to be completed by January 1, 1961.

(e) Spices, seasonings, essential oils, colorants, and natural extractives that are generally recognized as safe for their intended use, within the meaning of section 409 of the act, are as follows:

(1) SPICES AND OTHER NATURAL SEASONINGS AND FLAVORINGS (LEAVES, ROOTS, BARKS, BERRIES, ETC.)

Common name	Botanical name of plant source
Allspice	<i>Pimenta officinalis</i> Lindl.
Anise	<i>Pimpinella anisum</i> L.
Anise, star	<i>Illiolum verum</i> Hook. f.
Basil, sweet	<i>Ocimum basilicum</i> L.
Basil, bush	<i>Ocimum minimum</i> L.
Bay	<i>Laurus nobilis</i> L.
Calendula	<i>Calendula officinalis</i> L.
Capers	<i>Capparis spinosa</i> L.
Capsaicin	<i>Capsicum frutescens</i> L. or <i>Capsicum annuum</i> L.
Caraway	<i>Carum carvi</i> L.
Caraway, black (black cumin)	<i>Nigella sativa</i> L.
Cardamom (cardamon)	<i>Elettaria cardamomum</i> Maton.
Cassia, Chinese	<i>Cinnamomum cassia</i> Blume.
Cassia, Padang or Batavia	<i>Cinnamomum burmanni</i> Blume.
Cassia, Saigon	<i>Cinnamomum loureirii</i> Nees.
Cayenne pepper	<i>Capsicum frutescens</i> L. or <i>Capsicum annuum</i> L.
Celery seed	<i>Aptium graveolens</i> L.
Chives	<i>Allium schoenoprasum</i> L.
Cinnamon, Ceylon	<i>Cinnamomum zeylanicum</i> Nees.
Cinnamon, Chinese	<i>Cinnamomum cassia</i> Blume.
Cinnamon, Saigon	<i>Cinnamomum loureirii</i> Nees.
Clary (clary sage)	<i>Salvia sclarea</i> L.
Cloves	<i>Eugenia caryophyllata</i> Thunb.
Coriander	<i>Coriandrum sativum</i> L.
Cumin (cummin)	<i>Cuminum cyminum</i> L.
Cumin, black (black caraway)	<i>Nigella sativa</i> L.
Dill	<i>Anethum graveolens</i> L.
Fennel, common	<i>Foeniculum vulgare</i> Mill.
Fennel, sweet (finochchio, Florence fennel)	<i>Foeniculum vulgare</i> Mill. var. <i>dulce</i> (DC.) Alef.
Fenugreek	<i>Trigonella foenum-graecum</i> L.
Garlic	<i>Allium sativum</i> L.
Ginger	<i>Zingiber officinale</i> Rosc.
Glycyrrhiza	<i>Glycyrrhiza glabra</i> L. and other spp. of <i>Glycyrrhiza</i> .
Grains of paradise	<i>Amomum melegueta</i> Rosc.
Horseradish	<i>Armoracia lapathifolia</i> Gilib.
Lavender	<i>Lavandula officinalis</i> Chaix.
Licorice	<i>Glycyrrhiza glabra</i> L. and other spp. of <i>Glycyrrhiza</i> .
Mace	<i>Myristica fragrans</i> Houtt.
Marigold, pot	<i>Calendula officinalis</i> L.
Marjoram, pot	<i>Majorana onites</i> (L.) Benth.
Marjoram, sweet	<i>Majorana hortensis</i> Moench.
Mustard, black or brown	<i>Brassica nigra</i> (L.) Koch.
Mustard, brown	<i>Brassica juncea</i> (L.) Coss.
Mustard, white or yellow	<i>Brassica alba</i> (L.) Boiss.
Nutmeg	<i>Myristica fragrans</i> Houtt.
Oregano (oregano, Mexican oregano, Mexican sage, origanum)	<i>Lippia</i> spp.
Paprika	<i>Capsicum annuum</i> L.
Parsley	<i>Petroselinum crispum</i> (Mill.) Mansf.
Pepper, black	<i>Piper nigrum</i> L.
Pepper, cayenne	<i>Capsicum frutescens</i> L. or <i>Capsicum annuum</i> L.
Pepper, red	Do.
Pepper, white	<i>Piper nigrum</i> L.
Peppermint	<i>Mentha piperita</i> L.
Poppy seed	<i>Papaver somniferum</i> L.
Pot marigold	<i>Calendula officinalis</i> L.
Pot marjoram	<i>Majorana onites</i> (L.) Benth.
Rosemary	<i>Rosmarinus officinalis</i> L.
Rue	<i>Ruta graveolens</i> L.
Saffron	<i>Crocus sativus</i> L.
Sage	<i>Salvia officinalis</i> L.
Savory, summer	<i>Satureja hortensis</i> L. (<i>Satureja</i>).
Savory, winter	<i>Satureja montana</i> L. (<i>Satureja</i>).
Sesame	<i>Sesamum indicum</i> L.
Spearmint	<i>Mentha spicata</i> L.
Star anise	<i>Illiolum verum</i> Hook. f.
Tarragon	<i>Artemisia dracunculus</i> L.
Thyme	<i>Thymus vulgaris</i> L.
Turmeric	<i>Cureuma longa</i> L.
Vanilla	<i>Vanilla planifolia</i> Andr. or <i>Vanilla tahitensis</i> J. W. Moore
Zedoary	<i>Cureuma sedoaria</i> Rosc.

(3) ESSENTIAL OILS, OLEORESINS (SOLVENT-FREE), AND NATURAL EXTRACTIVES (INCLUDING DISTILLATES)

Common name	Botanical name or plant source
Allspice	<i>Pimenta officinalis</i> Lindl.
Almond, bitter (free from prussic acid)	<i>Prunus amygdalus</i> Batsch, <i>Prunus armeniaca</i> L., or <i>Prunus persica</i> (L.) Batsch.
Angelica root	<i>Angelica archangelica</i> L.
Angelica seed	Do.
Angelica stem	Do.
Angostura (cusparia bark)	<i>Galipea officinalis</i> Hancock.
Anise	<i>Pimpinella anisum</i> L.
Anafetida	<i>Ferula assa-foetida</i> L. and related spp. of <i>Ferula</i> .
Balsam of Peru	<i>Myroxylon pereirae</i> Klotzsch.
Basil	<i>Ocimum basilicum</i> L.
Bay leaves	<i>Laurus nobilis</i> L.
Bay (myrcia oil)	<i>Pimenta racemosa</i> (Mill.) J. W. Moore.
Bitter almond (free from prussic acid)	<i>Prunus amygdalus</i> Batsch, <i>Prunus armeniaca</i> L., or <i>Prunus persica</i> (L.) Batsch.
Bois de rose	<i>Aniba rosaeodora</i> Ducke.
Cananga	<i>Cananga odorata</i> Hook. f. and Thoms.
Capaicum	<i>Capicum frutescens</i> L. and <i>Capicum annuum</i> L.
Caraway	<i>Carum carvi</i> L.
Cardamon seed (cardamom)	<i>Elettaria cardamomum</i> Maton.
Carob bean	<i>Ceratonia siliqua</i> L.
Cascarilla bark	<i>Croton eluteria</i> Benn.
Cassia bark, Chinese	<i>Cinnamomum cassia</i> Blume.
Cassia bark, Padang or Batavia	<i>Cinnamomum burmanni</i> Blume.
Cassia bark, Saigon	<i>Cinnamomum loureirii</i> Nees.
Celeri seed	<i>Apium graveolens</i> L.
Chamomile flowers, Hungarian (camomile)	<i>Matricaria chamomilla</i> L.
Chamomile flowers, Roman or English (camomile)	<i>Anthemis nobilis</i> L.
Cherry, wild, bark	<i>Prunus serotina</i> Ehrh.
Chicory	<i>Chicorium intybus</i> L.
Cinnamon bark, Ceylon	<i>Cinnamomum zeylanicum</i> Nees.
Cinnamon bark, Chinese	<i>Cinnamomum cassia</i> Blume.
Cinnamon bark, Saigon	<i>Cinnamomum loureirii</i> Nees.
Cinnamon leaf, Ceylon	<i>Cinnamomum zeylanicum</i> Nees.
Cinnamon leaf, Chinese	<i>Cinnamomum cassia</i> Blume.
Cinnamon leaf, Saigon	<i>Cinnamomum loureirii</i> Nees.
Citronella	<i>Cymbopogon nardus</i> Rendle.
Citrus peels	<i>Citrus</i> spp.
Clary (clary sage)	<i>Salvia sclarea</i> L.
Clove bud	<i>Eugenia caryophyllata</i> Thunb.
Clove leaf	Do.
Clove stem	<i>Eugenia caryophyllata</i> Thunb.
Coca (decocainized)	<i>Erythroxylum coca</i> Lam. and other spp. of <i>Erythroxylum</i> .
Coffee	<i>Coffea</i> spp.
Cola nut	<i>Cola acuminata</i> Schott and Endl. and other spp. of <i>Cola</i> .
Coriander	<i>Coriandrum sativum</i> L.
Cumin (cummin)	<i>Cuminum cyminum</i> L.
Cusparia bark	<i>Galipea officinalis</i> Hancock.
Dill	<i>Anethum graveolens</i> L.
Zestrangle (esdrago, esdragon, tarragon).	<i>Artemisia dracunculus</i> L.
Fennel, sweet	<i>Foeniculum vulgare</i> Mill.
Penugreek	<i>Trigonella foenum-graecum</i> L.
Garlic	<i>Allium sativum</i> L.
Geranium, East Indian	<i>Cymbopogon martinii</i> Stapf.
Geranium, rose	<i>Pelargonium graveolens</i> L'Her.
Ginger	<i>Zingiber officinale</i> Rosc.
Glycyrrhiza	<i>Glycyrrhiza glabra</i> L. and other spp. of <i>Glycyrrhiza</i> .
Grapefruit	<i>Citrus paradisi</i> .
Guava	<i>Psidium</i> spp.
Hoarhound	<i>Marrubium vulgare</i> L.
Hope	<i>Humulus lupulus</i> L.
Jasmine	<i>Jasminum officinale</i> L. and other spp. of <i>Jasminum</i> .
Juniper (berries)	<i>Juniperus communis</i> L.
Kola nut	<i>Cola acuminata</i> Schott and Endl. and other spp. of <i>Cola</i> .
Laurel leaves	<i>Laurus nobilis</i> L.
Lavender	<i>Lavandula officinalis</i> Chaix.
Lavender, spike	<i>Lavandula latifolia</i> Vill.

ESSENTIAL OILS, OLEORESINS (SOLVENT-FREE), AND NATURAL EXTRACTIVES (INCLUDING DISTILLATES)—Continued

Common name	Botanical name of plant source
Lavandin.....	Hybrids between <i>Lavandula officinalis</i> Chaix and <i>Lavandula latifolia</i> Vill.
Lemon.....	<i>Citrus Limon</i> (L.) Burm. f.
Lemon grass.....	<i>Cymbopogon citratus</i> DC. and <i>Cymbopogon flexuosus</i> Stapf.
Licorice.....	<i>Glycyrrhiza glabra</i> L. and other spp. of <i>Glycyrrhiza</i> .
Lime.....	<i>Citrus aurantifolia</i> Swingle.
Locust bean.....	<i>Ceratonia siliqua</i> L.
Mace.....	<i>Myristica fragrans</i> Houtt.
Mandarin.....	<i>Citrus reticulata</i> Blanco.
Marjoram, sweet.....	<i>Majorana hortensis</i> Moench.
Must.....	<i>Flex paraguariensis</i> St. Hil.
Mustard.....	<i>Brassica</i> spp.
Naringin.....	<i>Citrus paradisi</i> Macf.
Neroli, bigarade.....	<i>Citrus aurantium</i> L.
Nutmeg.....	<i>Myristica fragrans</i> Houtt.
Onion.....	<i>Allium cepa</i> L.
Orange, bitter, flowers.....	<i>Citrus aurantium</i> L.
Orange leaf.....	<i>Citrus sinensis</i> (L.) Osbeck.
Orange, bitter, peel.....	<i>Citrus surantium</i> L.
Orange, sweet.....	<i>Citrus sinensis</i> (L.) Osbeck.
Origanum.....	<i>Origanum</i> spp.
Palmaroa.....	<i>Cymbopogon martini</i> Stapf.
Paprika.....	<i>Capsicum annuum</i> L.
Parsley.....	<i>Petroselinum crispum</i> (Mill.) Mansf.
Pepper, black.....	<i>Piper nigrum</i> L.
Pepper, white.....	<i>Piper nigrum</i> L.
Peppermint.....	<i>Mentha piperita</i> L.
Peruvian balsam.....	<i>Myroxylon pereirae</i> Klotzsch.
Petitgrain.....	<i>Citrus aurantium</i> L.
Petitgrain lemon.....	<i>Citrus Limon</i> (L.) Burm. f.
Petitgrain mandarin or tangerine.....	<i>Citrus reticulata</i> Blanco.
Pimenta.....	<i>Pimenta officinalis</i> Lindl.
Pimenta leaf.....	Do.
Pipissewa leaves.....	<i>Chimaphila umbellata</i> Nutt.
Pomegranate.....	<i>Punica granatum</i> L.
Prickly ash bark.....	<i>Xanthoxylum</i> (or <i>Zanthoxylum</i>) <i>Americanum</i> Mill. or <i>Xanthoxylum clava-herculis</i> L.
Rose absolute.....	<i>Rosa alba</i> L., <i>Rosa centifolia</i> L., <i>Rosa damascena</i> Mill., <i>Rosa gallica</i> L. and vars. of these spp.
Rose (otto of roses, attar of roses).....	Do.
Rose geranium.....	<i>Pelargonium graveolens</i> L'Her.
Rosemary.....	<i>Rosmarinus officinalis</i> L.
Rue.....	<i>Ruta graveolens</i> L.
Saffron.....	<i>Crocus sativus</i> L.
Sage.....	<i>Salvia officinalis</i> L.
Sage, Spanish.....	<i>Salvia lavandulacea</i> Vahl.
St. John's bread.....	<i>Ceratonia siliqua</i> L.
Schinus molle.....	<i>Schinus molle</i> L.
Spanish sage.....	<i>Salvia lavandulacea</i> Vahl.
Spearmint.....	<i>Mentha spicata</i> L.
Spike lavender.....	<i>Lavandula latifolia</i> Vill.
Tangerine.....	<i>Citrus reticulata</i> Blanco.
Tarragon.....	<i>Artemisia dracunculus</i> L.
Tea.....	<i>Thea sinensis</i> L.
Thyme.....	<i>Thymus vulgaris</i> L. and <i>Thymus syriacus</i> var. <i>gracilis</i> Boiss.
Thyme, white.....	Do.
Tuberose.....	<i>Pollanthes tuberosa</i> L.
Turmeric.....	<i>Curcuma longa</i> L.
Vanilla.....	<i>Vanilla planifolia</i> Andr. or <i>Vanilla tahitensis</i> J. W. Moore.
Violet leaves absolute.....	<i>Viola odorata</i> L.
Wild cherry bark.....	<i>Prunus serotina</i> Klrh.
Ylang-ylang.....	<i>Cananga odorata</i> Hook. f. and Thoms.
Zedoary bark.....	<i>Curcuma zedoaria</i> Rosc.

(8) MISCELLANEOUS

Common name	Derivation
Civet (sibeth, sibet, sibotum).....	<i>Civet cat</i> , <i>Viverra civetta</i> Schreber and <i>Viverra sibetha</i> Schreber.
Cognac oil, white and green.....	Ethyl cinnamate, so-called.
Musk (Tonquin musk).....	Musk deer, <i>Moschus moschiferus</i> L.